

irradiating the mixture with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture, while maintaining the mixture under a substantially no flow condition within the container in which the mixture is formed.

#### REMARKS

This Amendment is submitted in response to the Office Action mailed on April 9, 2002. Pursuant to the Office Action, Claims 28, 30, 32, 34, 38-47, 49 and 51 have been rejected under the judicially-created doctrine of obviousness type double patenting, Claims 28-30, 32, 34, 36 and 38-51 have been rejected under 35 U.S.C. § 112, Claims 40-42, 44, 45 and 49 under 35 U.S.C. § 102 and Claims 40-47, 49 and 51 under 35 U.S.C. § 103. In response, Claim 40 has been amended. In addition, Applicants note that they will file a Terminal Disclaimer upon notice of allowable subject matter in this application. With respect to the rejections under 35 U.S.C. § 112 and in view of the prior art, Applicants respectfully submit that the rejections have either been overcome or improper for the following reasons.

Addressing first the obviousness (35 U.S.C. § 103) rejections, Claims 28-30, 32, 34, 39-47, 49 and 51 have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,207,107 ('107 patent) and Claims 40-47, 49 and 51 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,445,629 ('629 patent) and *Rock* or *Walvik*.

These rejections are improper as a matter of law and fact. The '629 patent and '107 patent each issued after the above-identified patent application was filed. In this regard, this application claims priority to Serial No. 08/350,398 filed on December 6, 1994. Therefore, the two references can only constitute 102(e) prior art. 35 U.S.C. § 103 provides in pertinent part:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f), and (g) of Section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to same person.

The two references are assigned on their face to Baxter International. The instant application is assigned to Baxter International. Therefore, the two references do not constitute applicable prior art under 35 U.S.C. § 103 to the above-identified patent application. Therefore, the rejections under 35 U.S.C. § 103 are improper as a matter of law and fact and Applicants respectfully request that they be withdrawn.

Claims 40-42, 44, 45 and 49 stand rejected under 35 U.S.C. § 102(e) as being anticipated by the two above-identified Baxter patents ('107 and '629). In the spirit of cooperation, Claim 40 has been amended to specifically claim a port extending from a container. This port is not disclosed by either of the two patents. Therefore, the anticipation rejection has been overcome. Accordingly, Applicants respectfully request that it be withdrawn.

With respect to the 35 U.S.C. § 112 rejection, Applicants once again refer the Patent Office to their previous response with respect to the term "body fluid." It is clear that as used in the art, the term "body fluid" can be used as Applicants' have used same in their patent application. Furthermore, one of the basis tenants of patent law is that an applicant can define terms that are used in the specification. Clearly, the term "body fluid" has been defined in the specification. The definition is not contrary to the prior art. Indeed, Applicants have pointed out where patents have issued in the same art unit that is examining the instant application including the term "body fluid" as used by Applicants. Moreover, the Oxford Dictionary of Science defines "body fluid" similar to Applicants' definition. Therefore, Applicants respectfully submit that the term "body fluid" as used by Applicants in their claims is not indefinite and does comply with the mandates of 35 U.S.C. § 112. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Patent Office has also objected to the use of the word "sealed" as modifying container in Claims 28-30, 32, 34, 36, 38 and 39 as adding new matter. Applicants respectfully submit that this rejection is also improper and fails to consider Applicants' specification in its entirety. As set-forth in Applicants' patent application, the container can be a container such as used in the Optipat system that is disclosed in U.S. Patent No. 4,608,178. Clearly, that patent discloses "sealed containers." Furthermore, Applicants' patent application states that the container can be containers for housing blood and blood components available from the Fenwal Division of Baxter International. Such containers clearly must be sealed otherwise they could

not "contain" any fluid. Moreover, Figure 2 illustrates a sealed container otherwise the container walls would be flat, without any component contained within the interior.

Applicants respectfully submit that the Patent Office is using an incorrect interpretation of the law. Nowhere does the law require that every word that is used in the claim must be present verbatim in the specification in order to provide support, meet the written description requirement, or not add new matter. It is axiomatic that subject matter can be incorporated by reference. Further, it is axiomatic that subject matter can be provided by the drawings. The drawings clearly illustrate a sealed container. Applicants have incorporated by reference a patent that illustrates sealed containers. Additionally, Applicants have noted a commercially-available products that are sealed. Therefore, the Patent Office's rejection under 35 U.S.C. § 112 with respect to the term "sealed" is not proper and Applicants respectfully request it be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Please amend Claim 40 as follows:

40. (Amended) A method for inactivating viruses in a body fluid, the method comprising the steps of:

initially storing an amount of methylene blue in a container that includes an interior and at least one port extending from the container that provides controlled access to the interior, the container is constructed of a plastic material and includes an inner surface made of a non-polyvinyl chloride, plastic material;

forming a mixture by adding at least a portion of the amount of the methylene blue to an amount of the body fluid, by use of the port, wherein the portion of methylene blue is a virucidally effective amount of the methylene blue and further wherein the mixture formed is within either the container or in a second container that initially housed the body fluid; and

irradiating the mixture with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture, while maintaining the mixture under a substantially no flow condition within the container in which the mixture is formed.